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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,332	02/15/2002	Yuji Ishihara	2599 USOP	5909

7590 10/22/2003

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 10/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,332

Applicant(s)

ISHIHARA ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,2,4,6,14,16,22-29 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,4,6,14,16,25-29 and 31-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Amendment and response filed by applicants in Paper No. 12, dated July 7, 2003 have been entered and considered carefully. Claims 3, 17-21 and 30 have been canceled. Claims 1, 2, 4, 6, 14, 16, 22, 25-29, 31-39 are pending.

2. Initially, an error was observed and is hereby corrected. Please note that the election, which was made without any reason or pointing out any error, thus, non-traversal (see Paper No. 10, dated 2/26/03), was of group I claims 14 and claims 1-13, 15-21, 26-28, 30-39 reading on claim 14. Therefore, claims 22-24 should have been withdrawn and hereby withdrawn from consideration. Rejections of claims 22-24 of record are thus moot since they are withdrawn.

The subject matter, in the instantly amended claim 1, wherein R1-R2 forms homopiperidinyl, piprazinyl or homopiperazinyl ring are *non-elected*, and are *withdrawn* from consideration. Please note that the election of group I claim 14 was *without* traverse or reasoning, and claim 14 is limited to piperidinyl compounds.

Claims 25 and 29 as now amended can be prosecuted together with the elected piperidinyl compounds to the extent of the piperidinyl compounds.

Claims 1, 2, 4, 6, 14, 16, 25-29, 31-39 being drawn to the piperidinyl compound are pending and examined.

3. The specification is objected to as containing NEW MATTER.

37 CFR 1.118. Amendment of disclosure.

(a) No amendment shall introduce new matter into the disclosure of an application after filing date of the application (§ 1.53(b)). All amendments to the specification, including the claims, and the drawings filed after the filing date of the application must conform to at least one of them as it was at the time of the filing of the application. Matter not found in either, involving a departure from or an addition to the original disclosure, cannot be added to the application after its filing date even though supported by an oath or declaration in accordance with § 1.63 or § 1.67 filed after the filing date of the application.

(b) If it is determined that an amendment filed after the filing date of the application introduces new matter, claims containing new matter will be rejected and deletion of the new

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matter in the specification and drawings will be required even if the amendment is accompanied by an oath or declaration in accordance with § 1.63 or § 1.67.

Support for amendment of page 9, paragraph 4 is said to be found in example 25. Please note that in example 25, the compound is N-benzylidene which corresponds to the R4 group of the formula. This description does not support the amendment of page 9 where a general description with respect to the "optional substitution" on the aryl ring was concerned. Please note that benzylidene is Ph=C- moiety, which bonding is at the alkenyl site, thus, the "Ph=C-" is the substituent not a =C- was the on the aryl ring.

Support for amendment of page 14, paragraph is said to be found at page 5 line 14 and example 93. Please note that the trifluoroethyl of example 93 is on the N-phenyl while on page 5, the halogeno-C1-4 alkyl was on the "phenylalkyl", therefore, no support for any umbrella extrapolation to substitution on the aryl moiety. The description on page 5 was on benzyl which is not compound 93.

Support for amendment of page 17, paragraph 3 is said to be found at page 5. Please note that the paragraph bridging pages 4-5 of the specification described the phenyl substituents of R3 can be optionally substituted by haloalkyl or phenyl, therefore, arbitrary broadening this particular description to all moieties including imidolyl, amindino etc. can not be found.

To the extent that the scope of claims 1-13, 26-28, 30-39 with the term "optionally substituted" would now included the above amendments of the specification, the claims are **rejected** under 35 USC 112 first paragraph as containing NEW MATTER. Removal of all NEW MATTER is required. In re Resmussen 211 USPQ 325.

3. The rejection of claim 1 under 35 USC 112 second paragraph for the ambiguity of hydrocarbon moiety containing non-carbon or hydrogen structure is maintained for reason of record.

Applicants argued that this description is found on page 13 lines 6-34. Please note that at this particular section, it was found, hydrocarbon optionally substituted is referring "heterocyclic group optionally having a substituent" (line 15), therefore, what is the moiety? Which part is hydrocarbon which part is substituent? Does the heterocycle is being considered hydrocarbon? The Examiner does not have uncertainty, the basis of ambiguity is found in

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reading the specification which applicants should read carefully and not making self-conflicting arguments.

4. The rejection of claim 16 under 35 USC 112 second paragraph is changed to 35 USC 112 first paragraph in view of the amendment.

Claim 16 as it is amended now lacks description or enabling support that “ineffective” or “Toxic amount” of the compound would have the necessary utility and lacks descriptive and enabling support for what are the ineffective or toxic quantities in the specification.

5. The rejection of claim 15 under 35 USC 112 first paragraph for lacking adequate description on the scope “prodrug” is maintained. Please note that it was clearly delineated in the previous office action that no description as to target specific carrier, etc. prodrugs were found on page 26 lines 12-33. Applicants are urged to consult the textbook by Silverman (provided in previous office action) as to what one skilled in the art would considered being encompassed by the term “prodrug”. MPEP §2111 requires that the claims be interpreted by giving their broadest reasonable interpretation. If applicant’s intended scope are those prodrug modifications being limited to those as described on page 26 lines 12-33, then, it is recommended that the specific prodrugs found in the specification be incorporated in the claim.

6. The rejection of claim 28 under 35 USC 112 first paragraph is maintained for reason of record. The specific CCR5 antagonistic effective amount of the compounds in inhibiting HIV in spreading to uninfected cells as found on pages 106-108 does not provide enablement for the scope of the claims as suppressing all CCR5 receptor involved activities. Applicants are urged to consult the reference provided in the previous office action (CA 125) to the high unpredictability and limited understanding of chemokine receptor function in the art. In view of the documented high degree of unpredictability of chemokine receptor function, it is recommended that the specific inhibition of HIV infection of human peripheral blood mononuclear cells as described on page 2 be incorporated.

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7. The objection to claims 31-39 being essential duplicate of claims 4-12 is dropped in view of the amendment.

8. The rejections of claims 1-13, 15-16, 30-39 under 35 USC 103(a) over Kato or Kim in view of Caldwell, which are now applicable to the newly amended claims 1, 2, 4, 6, 16, 22, 25-29, 31-39 being drawn to the piperidinyl compounds are maintained for reason of record.

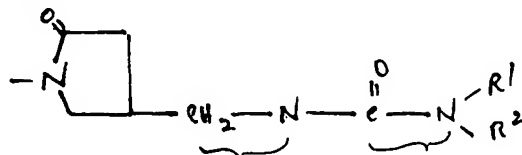
The claimed benefit of priority is denied because the certified translation verified that the invention as described in the priority document is not *the same invention* as the instant specification and claims. Particularly for example, the description of the instant specification on pages 4-5 are not found in the priority documents (compare translation p.9), the description on pages 9-10 are not found in the priority document (compare translation p.12), exhausted listing is not made but the examples described supra are evidence indicated that the instant specification and claims are not *the same invention* as the priority document.

The rejection of claims 1-13, 15-16, 30-39 over Kato or Kim in view of Caldwell are maintained since the priority documents evidence of no granting of priority benefit.

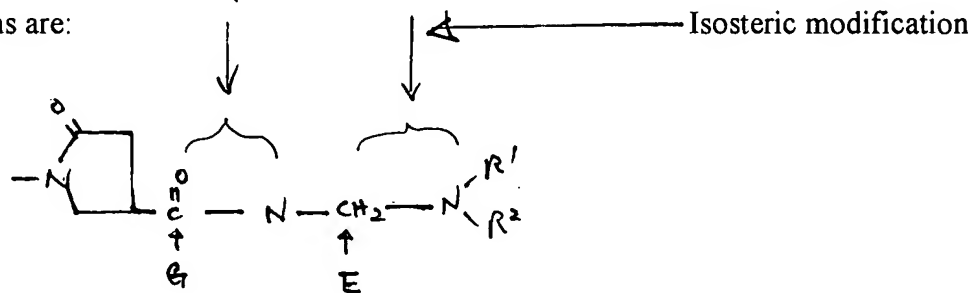
9. The rejection of claims 1-16, 30-39 under 35 USC 103(a) over Weber in view of Chepkova and Patani, which is now applicable to the newly amended claims 1, 2, 4, 6, 14, 16, 25-29, 31-39 being drawn to the piperidinyl compounds, is maintained for reason of record.

It is confusing as to what is the argument applicants is presenting and how did applicants chain using an amide bond isostere grew in size. It is urged that an understanding of chemical isostere based on Patani and Chepkova be noted, thus,

Weber's compounds are:



And the instant claims are:



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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

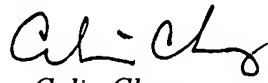
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang
Oct. 17, 2003


Celia Chang
Primary Examiner
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